


UNITED  HAYEK				DESIGN DOCUMENT		
REF:	RTX 11	REVISION:	1	PAGE:	1 OF 1	
TITLE:	EC Declaration of Conformity			DATE:	12-01-2018	

I, the undersigned, hereby declare that the products specified below conform with EC Directive 93/42/EEC, as amended by Directive 2007/47/EC, the Essential Requirements listed in Annex I, the Conformity Route requirements of Annex II excluding Paragraph 4 and with Statutory Instrument 2002 No. 618 The UK Medical Devices Regulations 2002.

Hayek RTX Respirator Systems Class IIb

This Declaration of Conformity is only valid in connection with the batch release documentation for the respective batches of Medical Devices manufactured during the validity of the CE certificate below. These batch records define the serial numbers concerned and covered by this Declaration.

United Hayek is exclusively responsible for this declaration of conformity

This declaration is supported by:

Notified Body 0120

SGS United Kingdom Limited.
Unit 202B, Worle Parkway,
Weston Super Mare,
Somerset, BS22 0WF
United Kingdom

CE (MDD/93/42/EEC) approval certificate (Annex II)

No. GB00/52285 issued by SGS

ISO 9001:2008 approval certificate

No. GB04/62667 issued by SGS

EN 13485:2012 approval certificate

No. GB00/52286 issued by SGS on

EN 13485:2012 (CMDCAS) approval certificate

No. GB04/3344 issued by SGS Canada

Signed:  _____

Date: 12th January 2018

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